

K053530 SONOACE X4 DIAGNOSTIC ULTRASOUND SYSTEMJan 3, 2006
15 days to decisionK053530 · Product code: **IYN** · Radiology
Source: <https://www.510kdatabase.net/k053530/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Dec 19, 2005
Decision date	Jan 3, 2006
Days to decision	15 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	Medison Co., Ltd.
Location	Media, PA, US
Contact	KYUNG-AM SHIM
Website	http://www.medison.com/
510(k) history	24 submissions · 24 cleared · 1990-2011

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k053530/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 17, 2026